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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,332	02/15/2002	Yuji Ishihara	2599 USOP	5909

23115 7590 05/17/2005

TAKEDA PHARMACEUTICALS NORTH AMERICA, INC  
INTELLECTUAL PROPERTY DEPARTMENT  
475 HALF DAY ROAD  
SUITE 500  
LINCOLNSHIRE, IL 60069

EXAMINER

CHANG, CELIA C

ART UNIT PAPER NUMBER

1625

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/030,332

Applicant(s)

ISHIHARA ET AL.

Examiner

Celia Chang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,7-9,11-16,22-29,32,34-36 and 38-41 is/are pending in the application.
- 4a) Of the above claim(s) 22-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,7-9,11-16,25-29,32,34-36 and 38-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Amendment and response filed by applicants dated Jan. 14, 2005 have been entered and considered carefully. Claims 3-4, 6, 10, 17-21, 30-31, 33 and 37 have been canceled. Claims 22-24 remain withdrawn. Claims 1-2, 7-9, 11-16, 25-29, 32, 34-36, 38-41 are pending. Claim 33 has been canceled, therefore, the inadvertent error of including claim 33 in the previous office action is hereby corrected.

2. The objection to the specification with respect to NEW MATTER has been corrected by restoring the specification to the original filing.

3. The rejection of claim 1 under 35 USC 112 second paragraph is maintained for reason of record.

Please note that the claim must "define" the meets and bounds of the scope. It was clearly pointed out the ambiguity of the specification with respect to the term "hydrocarbon" being inconsistent with the meaning of the term being made of only hydrogen and carbon, the meets and bounds can not be ascertained. Please note that the scope of the claims can not rely on the understanding of another in the art but must be "definitive" as defined by the applicants. It has been very carefully evaluated on the whole specification as delineated in the previous office action and "definition" for the term was not found but ambiguous examples made such term confusing.

4. The rejection of claim 15 under 35 USC 112 first paragraph is dropped in view of the amendment limiting to prodrugs disclosed on page 26.

5. The rejection of claim 28 under 35 USC 112 first paragraph is maintained for reason of record. Please note that the description of pages 106-108 are exclusively in vitro or cell culture.

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No support can be found for the now amended claim which can read on in a human. Please note a human cell line is not identical to in human.

6. The rejection of claims 1-2, 5, 7-8, 11-16, 25-29, 32, 34-36, 38-41 under 35 USC 103(a) over Kato CA 134 or Kim '994 in view of Caldwell '827 are maintained .

Please note that the amendment wherein E is trimethylene is NEW MATTER. It was in advertantly that this new matter rejection was not made. Therefore, the finality of the previous office action is withdrawn and the new matter rejection will be made as following.

The 103(a) rejections are maintained because upon removal of new matter, and restoration of the claims as originally filed, the obviousness rejection still applies.

7. Claim 1-2, 5, 7-8, 11-13, 15-16, 25-29, 32, 34-36, 38-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Please note that there is no antecedent basis for the instantly amended claim 1 wherein R3 is hydrocarbon or heterocyclic group optiaonlly substituted, R4 is.....etc. It is noted that a subgeneric disclosure for E being preferred C2-C6 polymethylene optionally having hydroxyl was found on page 5 lines 8-9 wherein the subgeneirc support is limited to conditions of [1] to [9] being met. No "subgeneric" disclosure supporting the instantly amended scope can be found. Applicants intended limitation of E is unsubstituted propylene would be considered new matter since such specific description for the instant amendment is lacking. See In re johson

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195 USPQ 187; Ex parte Grasseli 231 USPQ 393. Please note that many exemplified species having propylene can not support a "subgeneric" claim to contain such negative limitation.

This is a NEW MATTER rejection. Removal of all new matter is required. In re Russmussen 211 USPQ 325.

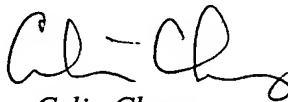
8. The denial of granting priority benefit has been clearly explained with comparative findings between the instant application and the certified translation of the priority document. Applicants are urged to consult the previous office action on page 6. Please note that the law requires that to gain benefit of priority date, the instant application must be the same invention as the priority document. Even if the instant application embraced "all" of the priority disclosure, if such discrepancy between the application and priority is found, a granting of the priority benefit must be denied.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang  
May 13, 2005

  
Celia Chang  
Primary Examiner  
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